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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/380,310      | 08/31/99    | UKAI                 | K 425-736P          |

002292 HM12/1113  
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EXAMINER

HAGHIGHATIAN, M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1619

DATE MAILED: 11/13/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

## Office Action Summary

Application No.

09/380,310

Applicant(s)

UKAI ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Receipt is acknowledged of preliminary amendments and status inquiry letter on respectively 8/31/99 and 9/26/00.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matoba et al (5,464,612) in view of Aoki et al (JP407267850) and further in view of Balkin et al (5,656,284).

Matoba et al teaches that medicinally active ingredients having an unpleasant taste may frequently have a basic group. These basic medications such as basic antibiotics, tend to have a strong bitter taste, (see col. 4, lines 36-60). It is, therefore, a known fact that bad tasting medications need to be altered in order to increase patient compliance .

Matoba et al and Aoki et al, both teach the use of anionic (or water-soluble) polymers, such as carrageenan and sodium alginates as well as gums in taste masking and as coating agents.

All three references cited, have teachings on the type of medications that are good choices for taste masking. These classes of medications are: antibiotics, anti depressives, antiallergics, etc, (see col. 4. Lines 1-30 of Matoba, and col. 6, lines 40-67 and col. 7, Lines 1-29 of Balkin).

Matoba teaches that generally basic medications have a bitter taste, and since donepezil hydrochloride is also a basic medication, it falls in the same class of medication in need of taste maskers.

The cephalosporine antibiotics are a class of medications of which, some contain basic groups. Cefpodoxime is one of these antibiotics that is named in teachings of Matoba and Balkin.

The amount of polymer used in masking flavors or as a coating agent is a matter of effectiveness and economy. Matoba reads " the amount can be adequately selected from within the range not interfering with the dissolution property or releasability and absorbability of the active ingredient according to the type of the active ingredient". Matoba suggests a range of about 1 to 1,000 parts, but more preferably from about 7 to 30 parts.

Matoba and Aoki teach that the dosage form of said preparation may be, for example, powders, fine granules, granules, pills, syrups, etc, (see col. 5, lines 39-44 of Matoba and Aoki).

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Balkin et al and Aoki et al both teach the method of preparing the composition, which is very generic method and known to all in the art.

It would have been obvious to a person of ordinary skill in the art at the time of invention to have modified the basic medication containing bitter taste, of Matoba et al with the teachings of Aoki and Balkin on the type of polymers usefull in masking the unpleasent taste of these medicinal active ingredients, because of the expectation of making them more palatable for patients, specifically infants, children, elderly, or those with difficulty swallowing tablets and capsules. The basic medications having unpleasent taste, the polymers, the method of preparation and the amounts of polymer needed are all known in the art.

### ***Conclusion***

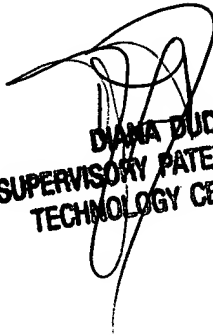
No claims are allowed at this time.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghghatian whose telephone number is 703-308-6330. The examiner can normally be reached on MON-FRI from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

  
**DIANA DUDASH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

Mina Haghghatian  
Patent Examiner  
Art Unit 1619

November 3, 2000